AUG 17 2011

CROSSER™ Recanalization System

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	FlowCardia, Inc 745 N. Pastoria Ave. Sunnyvale, CA 94085
Phone:	480-638-2939
Fax:	480-449-2546
Contact:	Timothy Wade, Regulatory Affairs Associate
Date	July 28, 2011

Subject Device Name:

Device Trade Name:	**CROSSER™ Recanalization System**
Common or Usual Name:	Peripheral Atherectomy Catheter (21 CFR 870.4875, Product Code MCW)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

- CROSSER™ System
  - Models: GEN200, CRU14S, CRU14P, CRU18 (K072776; cleared December 7, 2007)
  - Models: GEN200, CRUO14S, CRUO14P (K091119; cleared May 15, 2009)
  - Models: GEN200, CRUS6 (K092175; cleared February 17, 2010)
- Diamondback 360 Orbital Atherectomy System (K090521; cleared March 20, 2009)
- Jetstream System (K110626; cleared April 20, 2011)

Device Description:

The CROSSER™ Recanalization System is a high frequency mechanical vibration device designed for placement of guidewires through obstructed peripheral arteries by the removal or reduction of occlusive material. The system consists of an electronic CROSSER™ Generator, Foot Switch, high frequency Transducer, single-use CROSSER™ Catheter and sterile drape. The catheters are offered in a variety of configurations as shown in the table below. The system is required to be used with a power injector system for the delivery of saline. The CROSSER™ Catheter, which is intended for one procedure only, is connected to the CROSSER™ Generator through the high frequency Transducer. The Foot Switch is used to activate the CROSSER™ System. The CROSSER™ Generator and Transducer convert AC power into high frequency mechanical vibrations, which are propagated through a Nitinol core wire to the titanium or stainless steel tip of the CROSSER™ Catheter. The main body of the catheter is constructed from Pebax and a hydrophilic coating which covers the distal end of the catheter. The vibrational energy ablates intravascular plaque by mechanical impact and cavitational effects.

	CROSSER™ Catheters 14P and 14S		CROSSER™ Catheter 18	CROSSER™ Catheter S6
Working Length	146cm		125cm	154cm
Tip Outer Diameter	1.1mm (0.044")		1.5mm (0.061")	0.6mm (0.025")
Catheter Shaft Outer Diameter	**Rapid Exchange** 1.3mm (0.052")	**Over The Wire** 1.6mm (0.063")	1.5mm (0.058")	1.3mm (0.051")
Guidewire Lumen Length	**Rapid Exchange** 20cm	**Over The Wire** 152 cm	**Rapid Exchange** 20cm	n/a*
Guidewire Compatibility	0.014" (0.36mm)		0.018" (0.46mm)	n/a*
Guide Catheter Compatibility	6Fr (min ID 0.067" [1.7mm])		7Fr (min ID 0.080" [2.0mm])	5Fr (min ID 0.053") [1.3mm]
Sheath Compatibility	5Fr (min ID 0.067" [1.7mm])		6Fr (min ID 0.080" [2.0mm])	5Fr (min ID 0.053") [1.3mm]

* CROSSER™ Catheter S6 does not contain a guidewire lumen but creates a channel large enough to accommodate a guidewire up to 0.018".

Indications for Use of Device:

The CROSSER™ Recanalization System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions

via atherectomy. The device is contraindicated for use in the carotid arteries. The CROSSER™ Catheter is only intended for use with the CROSSER™ Generator. Refer to the CROSSER™ Generator Manual of Operations for proper use.

Review of the Modified Indications for Use:

The modified indication for use statement for the CROSSER™ Recanalization System does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices, the CROSSER™ System, the Diamondback System, and the Jetstream System. The modified indication clarifies the mechanism of action by which the CROSSER™ Recanalization System recanalizes a Chronic Total Occlusion (CTO) as the removal or reduction of occlusive material from the artery (atherectomy). The Diamondback System and Jetstream Systems are also indicated for the atherectomy of occlusive material in the peripheral arteries. Therefore, the subject device, the CROSSER™ Recanalization System, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The CROSSER™ Recanalization System has the following similarities to the predicate devices:

- Similar intended use (all predicates)
- Similar indications for use (all predicates)
- Same target population (all predicates)
- Same fundamental scientific technology (all predicates)
- Same operating principle (Crosser predicates)
- Similar operating principle (Diamondback and Jetstream predicates)
- Same mechanism of action (all predicates)
- Same materials (Crosser predicates)
- Same packaging materials and configuration (Crosser predicates)
- Same sterility assurance level and method of sterilization (Crosser predicates)

Performance Data:

To demonstrate substantial equivalence of the subject device, the CROSSER™ Recanalization System to the predicate devices, the technological characteristics and performance criterion were evaluated through bench testing. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, no additional *in vitro* tests or *in vivo* studies were required as the Crosser System previously met all requirements. As this 510(k) is clarifying the system mechanism of action, prior bench testing is presented.

Conclusions:
The subject device, the Crosser™ Recanalization System, satisfied the design requirements associated with the modified indications for use statement, as specified by applicable standards, guidance, test protocols and/or customer inputs. Therefore, the Crosser™ Recanalization System is substantially equivalent to the legally marketed predicate devices, the Crosser™ System, the Diamondback System, and the Jetstream System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th St. NW
Buffalo, MN 55313

SEP 18 2013

Re: K112308
Trade/Device Name: Crosser Recanalization System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: August 10, 2011
Received: August 11, 2011

Dear Mr. Job:

This letter corrects our substantially equivalent letter of August 17, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112308

Device Name: CROSSER™ Recanalization System

Indications for Use: The CROSSER™ Recanalization System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The device is contraindicated for use in carotid arteries.

The CROSSER™ Catheter is only intended for use with the CROSSER™ Generator. Refer to the CROSSER™ Generator Manual of Operations for proper use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112308